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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,480	02/26/2004	Daniel P. Silver	20363-011 CON	8561

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7590 12/27/2006

EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/789,480	Applicant(s) SILVER ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,7-11 and 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 12-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 7 August 2006 in response to the Non-Final Office Action mailed 5 May 2006. Claims 1-5, 7-11 and 26-34 were withdrawn from consideration and claims 6 and 12-25 were considered in the 5 May Office Action. Claims 6, 16, 21 and 22 were amended in the 7 August Paper. Claims 1-34 are pending and claims 6 and 12-25 are under consideration.

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

Claims 6 and 12-25 **stand rejected** under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As stated in the 5 May Office Action, claims 6, 14, 15, 21, 22, 24 and 25 are indefinite in the recitation “said recombinase” because the antecedent basis for the limitation is unclear. Claim 6 uses the phrase “a recombinase” twice in lines 25-26 (*i.e.*, “a recombinase gene operably linked to an expression control sequence” and “signal sequences recognized by a recombinase”). As according to the broadest reasonable interpretation of the claim the recombinase gene and the recombinase that recognizes the signal sequences need not be the same, there are possibly two distinct recombinases in claim 6. It is unclear which recombinase is being referred to as “said recombinase” subsequently in claim 6 and in the dependent claims.

Claims 12, 13, 16-20 and 23 are indefinite insofar as they depend from claim 6.

Response to Arguments

In response to the *prima facie* rejection Applicant contends that the subsequent recitations of “the [or said] recombinase” can only be referring to the recombinase and not to the recombinase gene because the subsequent recitations do not explicitly state “recombinase gene”.

This argument has been fully considered but is not deemed persuasive. Lines 3-4 of the instant claim 6 read as follows, “a first nucleic acid molecule comprising a recombinase gene operably linked to an expression control sequence and signal sequences recognized by a recombinase.” There are two recombinases described in this phrase. The first is the recombinase encoded by the recombinase gene and the second is the recombinase that recognizes the signal sequences. As both recitations use an indefinite article, these two recombinases need not be the same (i.e., the signal sequences need not be recognized by the recombinase encoded by the recombinase gene). Subsequently, the claims refer to “the [or said] recombinase” without making any distinction between the recombinase encoded by the recombinase gene and the recombinase that recognizes the signal sequences. For example, claim 6, lines 7-8 recite, “wherein said recombinase, when expressed in said cell, excises a sequence in said first nucleic acid molecule...” In that case, if “said recombinase” refers to the recombinase encoded by the recombinase gene, then the claim requires that the recombinase encoded in the first nucleic acid molecule be capable of excising a sequence in the first nucleic acid molecule. In contrast, if the antecedent basis for “said recombinase” is the recombinase that recognizes the signal sequences, then the recombinase encoded the recombinase gene need not be capable of “excising a sequence in said first nucleic acid molecule” because the excising might be carried out by any recombinase that recognizes the signal sequences irrespective of whether it is the same as or different from the

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recombinase encoded by the first nucleic acid molecule. Given that the scope of the claim is significantly different depending upon whether the antecedent of "said recombinase" is the recombinase encoded by the first nucleic acid or the recombinase that recognizes the signal sequence and the disclosure provides no means to clearly ascertain which meaning is intended, the metes and bounds of the claims as a whole are unclear.

Rejection of claim 6 as further indefinite because it is unclear whether the claim requires that the recombinase gene be operably linked to the signal sequences recognized by a recombinase is **withdrawn** in view of the claim amendments.

Rejection of claim 16 as further indefinite in the reciting that the tissue of the plant is edible or inedible is **withdrawn** in view of the claim amendments.

Rejection of claims 21 and 22 as further indefinite in reciting, "said region encoding said recombinase" is **withdrawn** in view of the claim amendments.

Claim Rejections - 35 USC § 102

Claims 6, 12, 17-23 and 25 **stand rejected** under 35 U.S.C. 102(a or e) as being anticipated by Hodges *et al.*, US Patent No. 5,929,307. This rejection is maintained for the reasons set forth in the 5 May Office Action, beginning at page 5, and for the reasons set forth herein below in the response to Applicant's arguments.

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Response to Arguments

In response to the *prima facie* rejection of record, Applicant contends, “The present invention discloses in one embodiment a first nucleic acid molecule comprising a recombinase gene operably linked to an expression control sequence and signal sequences recognized by a recombinase operably linked to the recombinase gene and a second nucleic acid molecule comprising a target gene and signal sequences recognized by the same recombinase as required by claim 6.” Applicant contends that the Hodges construct does not anticipate the claims because the recombinase gene in the Hodges construct is not linked to signal sequences recognized by that same recombinase.

This argument has been fully considered but is not deemed persuasive. As discussed above with regard to the rejection under 35 USC §112, second paragraph, the instant claim can be construed as not requiring that the recombinase which recognizes the signal sequences comprised by the nucleic acids be the same as the recombinase encoded by the first nucleic acid. Because the antecedent basis for “said recombinase” in the claims might be independently construed as either one of the recombinase encoded by the recombinase gene or the recombinase that recognizes the signal sequences, these two recombinases need not be the same (i.e., the signal sequences need not be recognized by the recombinase encoded by the recombinase gene). If the antecedent basis for the subsequent recitations of “said recombinase” is the recombinase that recognizes the signal sequences, then the recombinase encoded the recombinase gene need not be capable of “excising a sequence in said first nucleic acid molecule” because the excising might be carried out by any recombinase that recognizes the signal sequences irrespective of whether it is the same as or different from the recombinase encoded by the first nucleic acid

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molecule. Therefore, the broadest reasonable construction of the claim encompasses an embodiment wherein the signal sequences comprised by the second nucleic acid molecule are not the same as the signal sequences recognized by the recombinase encoded by the first nucleic acid.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102 as anticipated by the art.

Rejection of claims 6, 17-23 and 25 under 35 U.S.C. 102(b) as being anticipated by Anderson *et al.*, US Patent No. 5,629,159 (made of record in the IDS filed 26 February 2004) is **withdrawn** in view of the claim amendments and Applicant's arguments with regard thereto.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation, "the signal sequences for the first nucleic acid and the second nucleic acid are not the same sequences". It is unclear whether this limitation requires that the signal sequences not be recognized by the same recombinase, might be

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recognized by the same recombinase but must not comprise the base same sequence¹, or might be recognized by the same recombinase and comprise the same base sequence but cannot be located at the same position in the molecule (i.e., first and second sites must not be one and the same). Because these alternative interpretations result in claims of substantially different scope and the disclosure provides no means to clearly establish which one of the interpretations is intended, the metes and bounds of the claims as a whole are unclear.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

¹ Many site specific recombinases recognize sequence other than their canonical substrate sequence.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.

Primary Examiner

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